

09/673,411

Page 4

Upon amendment, the above-identified application will have three independent claims (amended Claim 1 and new Claims 31 and 32) and 28 total claims (amended Claims 1, 3, 4, 9, and 13-15 and new Claims 18-38). The Applicant previously paid for at least three independent claims and 20 total claims. Therefore, a fee is due for eight excess total claims; and payment of the fee is described in the enclosed fee-calculation sheet.

Support for amended Claim 1 can be found in, inter alia, originally filed Claims 1-3. Support for amending Claims 3, 4, and 9 can be found in, inter alia, originally filed Claims 3, 4, and 9, respectively.

Support for amended Claim 13 can be found in, inter alia, originally filed Claim 5. Support for amended Claim 14 can be found in, inter alia, originally filed Claim 8. Support for amended Claim 15 can be found in, inter alia, originally filed Claim 4.

Support for new Claims 18 and 19 can be found in, inter alia, originally filed Claim 9. Support for new Claim 20 can be found in, inter alia, originally filed Claim 7. Support for new Claim 21 can be found in, inter alia, originally filed Claims 7 and 8. Support for new Claims 22 and 24 can be found in, inter alia, originally filed Claim 8. Support for new Claim 23 can be found in, inter alia, originally filed Claim 5. Support for new Claims 25-28 can be found in, inter alia, lines 9-14 on page 3 and lines 14-17 on page 6 of the specification. Support for new Claims 29, 30, 33, and 36 can be found in, inter alia, Example A, which is described in line 8 on page 4 through the last line on page 6 of the specification.

Support for new Claim 31 can be found in, inter alia, originally filed Claims 1 and 2 and the table at the top of page 5 of the

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specification. Support for new Claim 32 can be found in, inter alia, originally filed Claims 1 and 2, the table at the top of page 5 of the specification, and the first table on page 7 of the specification. The table at the top of page 5 of the specification lists Sepigel 305; however, new Claims 31 and 32 refer to polyacrylamide, C₁₃-C₁₄ isoparaffin, and laureth-7, rather than to Sepigel 305, because Sepigel 305 comprises polyacrylamide, C₁₃-C₁₄ isoparaffin, and laureth-7. (We are enclosing herewith a 7-page GE document entitled "Datasheet for SF1632," which indicates in the penultimate item in the table on page 4 of the document and in footnote number 3 on page 4 of the document that Sepigel 305 comprises polyacrylamide, C₁₃-C₁₄ isoparaffin, and laureth-7.)

Support for new Claims 34, 35, 37, and 38 can be found in, inter alia, originally filed Claims 2 and 3.

In items 1-3 on pages 2-3 of the outstanding Office Action, the Examiner rejects currently pending Claims 7, 13, and 16 for allegedly being indefinite. The Applicant respectfully traverses this rejection. Furthermore, this rejection is now moot and should be withdrawn because currently pending Claims 7 and 16 are being deleted, and amended Claim 13 is not indefinite to someone with ordinary skill in the art.

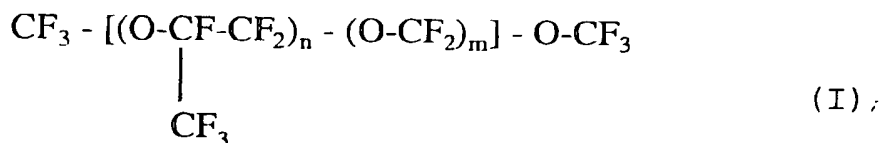
In items 6-8 on pages 5-7 of the outstanding Office Action, the Examiner rejects currently pending Claims 1, 3, 4, 6, 7, 9, and 13-17 for allegedly being obvious over European Patent Publication No. 0390206 A2 (hereinafter referred to as the "Barz document") in view of Gross et al.'s U.S. Patent No. 5,686,102. The Applicant respectfully traverses this rejection because the prior art does not teach or suggest the claimed invention; and the Applicant also respectfully traverses this rejection for the reasons that are set forth below.

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Amended independent Claim 1 claims a pharmaceutical composition comprising:

- (1) one or more active ingredients;
- (2) between 0.01 per cent and 60 per cent by weight of a compound of formula I

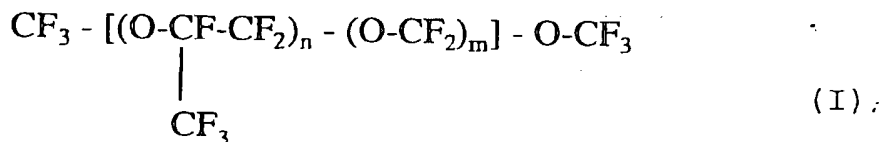


with n and m > 18 and < 46 and with a molecular weight between about 600 and about 8,000; and

- (3) 0.01% to 10% by weight of phosphatidylcholine.

New independent Claims 31 and 32 each claim a pharmaceutical composition consisting essentially of:

- (1) one or more active ingredients;
- (2) between 0.01 per cent and 60 per cent by weight of a compound of formula I



with n and m > 18 and < 46 and with a molecular weight between about 600 and about 8,000;

- (3) phosphatidylcholine; and
- (4) optionally other ingredients.

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Amended independent Claim 1 and new independent Claims 31 and 32 are nonobvious over the prior art because the prior art does not teach or suggest the claimed pharmaceutical composition, which produces superior trans-absorption of the active ingredient (e.g., over 5-20 times the normal trans-absorption) because the claimed pharmaceutical composition includes the compound of formula I and phosphatidylcholine in addition to the active ingredient.

The Gross patent (column 1, lines 54-60) discloses a pharmaceutical composition for topical administration comprising an active ingredient, a fluorocarbon, and phosphatidylcholine. According to the Gross patent, Gross's pharmaceutical composition is designed to ensure deeper penetration into the skin and transdermal transport. Specifically, according to the Gross patent (column 3, lines 55-62), the fluorocarbon (with the active ingredient and the phosphatidylcholine) must be able to penetrate into the deeper-lying regions of the skin.

The Gross patent teaches that only some fluorocarbons are suitable for penetrating into the deeper-lying regions of the skin; and according to the Gross patent (column 3, lines 16-19), suitable fluorocarbons include:

perfluoroethers, such as aliphatic ethers, F-alkylfurans, bicyclic and substituted bicyclic ethers having either 2 or 3 oxygen atoms in the molecule, e.g., perfluorodihexyl ethers, perfluorobutyltetrahydrofuran, perfluoropolyethers.

In the Gross patent, "perfluorodihexyl ethers" are listed as examples of aliphatic ethers; "perfluorobutyltetrahydrofuran" is listed as an example of F-alkylfurans; and "perfluoropolyethers"

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are listed as examples of bicyclic and substituted bicyclic ethers having either 2 or 3 oxygen atoms in the molecule. Thus, the Gross patent discloses that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin include bicyclic and substituted bicyclic perfluoropolyethers having either 2 or 3 oxygen atoms in the molecule. Significantly, the Gross patent does not disclose or suggest that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin may include acyclic perfluoropolyethers; and, more specifically, the Gross patent does not disclose or suggest that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin may include the acyclic perfluoropolyether compound of formula I, as claimed in amended Claim 1 and in new Claims 31 and 32.

Other sections of the Gross patent disclose suitable fluorocarbons for penetrating into the deeper-lying regions of the skin, but nowhere does the Gross patent teach or suggest that the acyclic perfluoropolyether compound of formula I is a suitable fluorocarbon. For instance, Table 1 of the Gross patent (see column 5, lines 37-55) lists numerous suitable fluorocarbons, but none of the fluorocarbons that are listed in Table 1 are perfluoropolyethers. Similarly, all of the working examples in the Gross patent (see Examples 1-5 at column 5, line 56 through column 6, line 46) use perfluorodecalin and F-dibutylmethylaniline, which are not perfluoropolyethers.

As explained in the two preceding paragraphs, the Gross patent suggests that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin may include bicyclic perfluoropolyethers, but the Gross patent does not provide specific working examples or specific theoretical examples of suitable bicyclic perfluoropolyethers. More importantly, the Gross patent does not teach or suggest that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin may

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include acyclic perfluoropolyethers; and the Gross patent does not teach or suggest that suitable fluorocarbons for penetrating into the deeper-lying regions of the skin may include the acyclic perfluoropolyether compound of formula I, as claimed in amended Claim 1 and in new Claims 31 and 32.

Because the Gross patent does not teach or suggest the acyclic perfluoropolyether compound of formula I (as claimed in amended Claim 1 and in new Claims 31 and 32), the Examiner turns to the Barz document, which discloses a cosmetic composition comprising a an acyclic perfluoropolyether compound of formula I (see line 25 on page 7 of the Barz document) and other components. However, the Barz document (page 7, line 2) also teaches that the fluorinated compounds (e.g., the acyclic perfluoropolyether compound of formula I) are "not absorbed by the skin." And because the Barz document indicates that the acyclic perfluoropolyether compound of formula I does not penetrate into the deeper-lying regions of the skin, the Barz document teaches away from the Gross patent, which specifies that the fluorocarbons in Gross's pharmaceutical composition must be able to penetrate into the deeper-lying regions of the skin (see column 3, lines 55-62 in the Gross patent).

Given that the Barz document teaches away from the Gross patent, someone with ordinary skill in the art at the time that the Applicant's claimed invention was made would not have been motivated to use Barz's acyclic perfluoropolyether compound of formula I (see line 25 on page 7 of the Barz document) as the fluorocarbon in Gross's pharmaceutical composition. The Gross patent discloses a pharmaceutical composition comprising a fluorocarbon that must be able to penetrate into the deeper-lying regions of the skin, while the Barz document indicates that the acyclic perfluoropolyether compound of formula I does not penetrate into the deeper-lying regions of the skin. Therefore,

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rather than teaching that the acyclic perfluoropolyether compound of formula I should be used as the fluorocarbon in Gross's pharmaceutical composition, the prior art actually teaches that the acyclic perfluoropolyether compound of formula I (as claimed in amended Claim 1 and in new Claims 31 and 32) should not be used as the fluorocarbon in Gross's pharmaceutical composition because, according to the Barz document, the acyclic perfluoropolyether compound of formula I does not penetrate into the deeper-lying regions of the skin. Furthermore, as explained above in paragraph 2 on page 6 through paragraph 1 on page 9 of this supplemental response, the Gross patent does not even teach or suggest that acyclic perfluoropolyethers, such as the acyclic perfluoropolyether compound of formula I (as claimed in amended Claim 1 and new Claims 31 and 32), would be suitable fluorocarbons for penetrating into the deeper-lying regions of the skin. Consequently, there is nothing in the prior art that would motivate someone with ordinary skill in the art to use the acyclic perfluoropolyether compound of formula I as the fluorocarbon in Gross's pharmaceutical composition. In fact, the prior art teaches that the acyclic perfluoropolyether compound of formula I (as claimed in amended Claim 1 and in new Claims 31 and 32) should not be used as the fluorocarbon in Gross's pharmaceutical composition because, according to the Barz document, the acyclic perfluoropolyether compound of formula I does not penetrate into the deeper-lying regions of the skin. And because the prior art does not teach or suggest the Applicant's claimed pharmaceutical composition (which includes an active ingredient, the acyclic perfluoropolyether compound of formula I, and phosphatidylcholine), amended independent Claim 1 and new independent Claims 31 and 32 are nonobvious over the prior art.

Amended independent Claim 1 is also nonobvious over the prior art because amended Claim 1 claims a pharmaceutical composition comprising 0.01% to 10% by weight of phosphatidylcholine, while

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the Gross patent (column 1, lines 59-60) calls for 30-99% by weight of phosphatidylcholine. Because the pharmaceutical composition that is claimed in amended Claim 1 uses significantly less phosphatidylcholine than suggested by the prior art, amended Claim 1 is further nonobvious over the prior art.

In addition, new independent Claims 31 and 32 are further nonobvious over the prior art because new Claims 31 and 32 omit one or more ingredients that are required by the prior art.

All of the other claims (amended Subclaims 3, 4, 9, 13-15, and new Subclaims 18-30 and 33-38) are nonobvious over the prior art because they are each directly or indirectly dependent on a nonobvious base claim (amended independent Claim 1, new independent Claim 31, or new independent Claim 32). In addition, all of these subclaims are further nonobvious over the prior art because they each claim features that are not disclosed or suggested by the prior art.

For example, amended Subclaims 9 and 17 and new Subclaims 18 and 19 are further nonobvious over the prior art because they each claim a pharmaceutical composition wherein trans-absorption of the active ingredient is increased by up to more than five times its normal value. New Subclaims 25 and 27 are further nonobvious over the prior art because they each claim a pharmaceutical composition wherein trans-absorption of the active ingredient is increased by up to more than ten times its normal value. New Subclaims 26 and 28 are further nonobvious over the prior art because they each claim a pharmaceutical composition wherein trans-absorption of the active ingredient is increased by up to more than 20 times its normal value. Since the prior art does not teach or suggest pharmaceutical compositions with such increased trans-absorption, amended Subclaims 9 and 17 and new Subclaims 18, 19, and 25-28 are further nonobvious over the prior art.

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New Subclaims 29, 30, 33, and 36 are further nonobvious over the prior art because they each claim a pharmaceutical composition having troxerutine as the active ingredient. The Gross patent discloses pharmaceutical compositions comprising numerous active ingredients, but the Gross patent does not teach or suggest that troxerutine is a suitable active ingredient. Therefore, new Subclaims 29, 30, 33, and 36 are further nonobvious over the prior art.

This supplemental response amends the specification and the abstract to correct each instance of formula I. Support for correcting formula I in the specification and the abstract can be found in, inter alia, lines 7-8 on page 10 of the specification. Line 7 sets forth the chemical name for the corrected formula I; and line 8 indicates that the C.A.S. number for the corrected formula I is C.A.S. number 69991-67-9. In addition, as shown in the enclosed document entitled "Product Number: 374458," the corrected formula I is consistent with the molecular formula that for C.A.S. number 69991-67-9.

In view of the foregoing, favorable reconsideration of the amended application is respectfully requested. It is submitted that the claims of record are in condition for allowance. Allowance of the claims at an early date is solicited.

This supplemental response cancels currently pending Claims 2, 6, 7, 8, 16, and 17, amends currently pending Claims 1, 3, 4, 9, and 13-15, and adds new Claims 18-38. The cancellations, amendments, and additions that are described in the preceding sentence were done to claim the scope of the invention that the Applicant elects to claim and were not done to overcome the prior art, were not done to overcome rejections under 35 U.S.C. § 112, and were not done to overcome any other rejections or objections. The

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cancellations, amendments, and additions that are described in the first sentence of this paragraph shall not be considered necessary to overcome the prior art, shall not be considered necessary to overcome rejections under 35 U.S.C. § 112, and shall not be considered necessary to overcome any other rejections or objections.

The Applicant reserves the right to seek protection for any unclaimed subject matter either subsequently in the prosecution of the present case or in a divisional or continuation application.

The Commissioner is authorized to charge any additional fees which may be required or credit overpayment to Deposit Account No. 12-0415. In particular, if this response is not timely filed, then the Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 C.F.R § 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed; and the petition fee due in connection therewith may be charged to deposit account No. 12-0415.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C., 20231 on

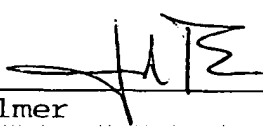
April 9, 2002
(Date of Deposit)

JOHN PALMER
(Name of Applicant, Assignee
or Registered Representative)

(Signature)

(Date)

Respectfully submitted,


John Palmer
Reg. No. 36,885
LADAS & PARRY
5670 Wilshire Boulevard
Suite 2100
Los Angeles, California 90036
(323) 934-2300

Enclosures: A 7-page GE document entitled "Datasheet for SF1632"
Appendices A, B, C, D, E, F, and G
A document entitled "Product Number: 374458"

Appendix A

RE: U.S. Patent Application No. 09/673,411

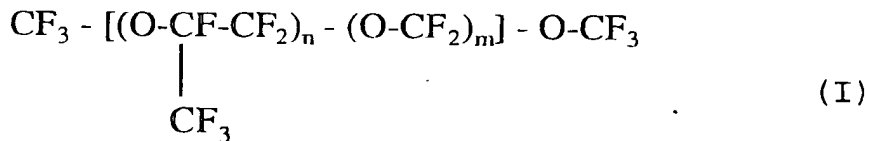
Applicant: Norberto FESTO

Title: Pharmaceutical Compositions Containing Compounds...

Our Ref.: B-3992PCT 618156-1/JP/KST

Please replace currently pending Claims 1, 3, 4, 9, and 13-15 with amended Claims 1, 3, 4, 9, and 13-15, which are set forth below.

1. (Amended twice) A pharmaceutical composition comprising,
apart from one or more active ingredients,
 - between 0.01 per cent and 60 per cent by weight of a
compound of formula I



with n and m > 18 and < 46 and with a molecular weight between about 600 and about 8,000 in combination with 0.01% to 10% by weight of phosphatidylcholine for enhancement of active-ingredient absorption.

3. (Amended twice) A pharmaceutical composition according to claim 1 with 0.1 per cent to 30 per cent by weight of the

Appendix A

compound of formula I with n and $m > 24$ and < 36 and with the molecular weight between 1,000 and 4,000.

- (2
Cont.
4. (Amended twice) A pharmaceutical composition according to claim 1, wherein the composition comprises other compatible ingredients and is in a form selected from the group consisting of creams, emulsions, ointments, lotions, foams, gels, aspersion powders, and transdermal formulations.
-

- (3
9. (Amended twice) The method according to Claim 13, wherein trans-absorption of the active ingredient is increased by up to more than five times its normal value.
-

13. (Amended once) A method for enhancing absorption of an active ingredient, wherein the method comprises topically applying the pharmaceutical composition claimed in Claim 1 to a patient in need thereof, wherein the active ingredient is absorbed through derma, cutis, mucosa, rectum, vagina, or urethra.

14. (Amended once) The method according to Claim 13, wherein the active ingredient comprises Troxerutine, Nimesulide, or a non-steroidal anti-inflammatory drug, wherein said non-steroidal anti-inflammatory drug comprises Ketoprofen, Diclofenac Sodium, Ibuprofen, Etodolic Acid, or Piroxicam.

15. (Amended once) A pharmaceutical composition according to Claim 3, wherein the composition comprises other compatible ingredients and is in a form selected from the group consisting of creams, emulsions, ointments, lotions, foams, gels, aspersion powders, and transdermal formulations.
-

Appendix B

RE: U.S. Patent Application No. 09/673,411

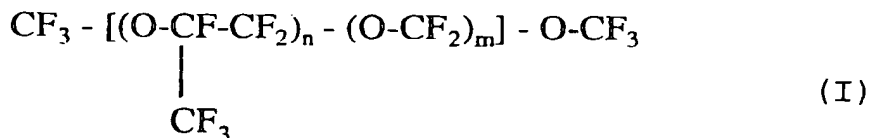
Applicant: Norberto FESTO

Title: Pharmaceutial Compositions Containing Compounds...

Our Ref.: B-3992PCT 618156-1/JP/KST

Please amend currently pending Claims 1, 3, 4, 9, and 13-15 as indicated below, wherein the portions being added are underlined and the portions being deleted are enclosed in braces.

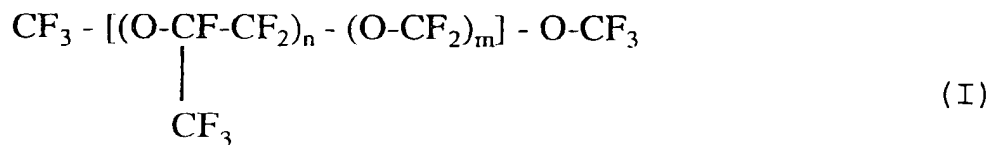
1. (Amended twice) {Pharmaceutical compositions} A
pharmaceutical composition comprising, apart from one or more active {ingredient(s)} ingredients,
 - between {about} 0.01 per cent and {about} 60 per cent by weight of {the compounds} a compound of formula I



with n and m > 18 and < 46 and with a molecular {weights} weight between about 600 and about 8,000 in combination with {between about 0.01 per cent and about 20 per cent} 0.01% to 10% by weight of {Phosphatidycholine, as compounds with activity} phosphatidylcholine for {the} enhancement of active-ingredient absorption.

Appendix B

3. (Amended twice) {Pharmaceutical compositions} A pharmaceutical composition according to claim 1 with {about} 0.1 per cent to {about} 30 per cent by weight of the {compounds} compound of formula I with n and m > 24 and < 36 and with the molecular {weights} weight between {about} 1,000 and {about} 4,000 {and with about 0.1 per cent to about 10 per cent by weight of Phosphatidylcholine}.
4. (Amended twice) {Pharmaceutical compositions} A pharmaceutical composition according to claim 1, {containing} wherein the composition comprises other compatible ingredients and {being present in the} is in a form selected from the group consisting of creams, emulsions, ointments, lotions, foams, gels, aspersion powders, and transdermal formulations.
9. (Amended twice) The method according to Claim 13, wherein trans-absorption of {drugs} the active ingredient is increased by up to more than five times its normal value.
13. (Amended once) A method for enhancing {of} absorption of an active ingredient{s of pharmaceutical compositions}, {said} wherein the method comprises topically applying the pharmaceutical composition{s} claimed in Claim 1 to a patient in need thereof, {being designed for topical external or internal applications, said} wherein the active ingredient{s being} is absorbed through derma, cutis, mucosa, rectum, vagina, {and} or urethra{, said method comprising using compounds of formula (I)}

Appendix B

wherein n and m is each within a range of more than 18 and less than 46, preferably within a range of more than 24 and less than 36, and with molecular weights between about 600 and about 8,000, preferably between about 1,000 and about 4,000}.

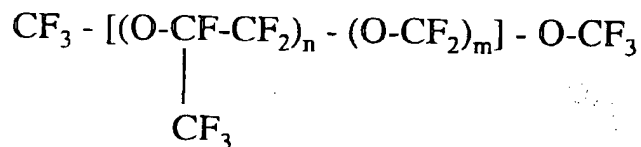
14. (Amended once) The method according to Claim {7} 13, wherein the active ingredient comprises {drugs} Troxerutine, Nimesulide {and} or a non-steroidal anti-inflammatory drug{s are used}, wherein said non-steroidal anti-inflammatory drug{s comprising} comprises Ketoprofen, Diclofenac Sodium, Ibuprofen, Etodolic Acid, {and} or Piroxicam.
15. (Amended once) {Pharmaceutical compositions} A pharmaceutical composition according to Claim 3, {containing} wherein the composition comprises other compatible ingredients and {being present} is in a form selected from the group consisting of creams, emulsions, ointments, lotions, foams, gels, aspersion powders, and transdermal formulations.

Appendix CPAGE 1 OF 3

RE: U.S. Patent Application No. 09/673,411
Applicant: Norberto FESTO
Title: Pharmaceutical Compositions Containing Compounds...
Our Ref.: B-3992PCT 618156-1/JP/KST

Please replace the first paragraph on page 3 of the specification (see page 3, lines 1-8) with the amended paragraph as set forth below.

The term PFPE means molecules with a chemical structure



where $n/m = 20=40$

with molecular weights between 650 and 6250,

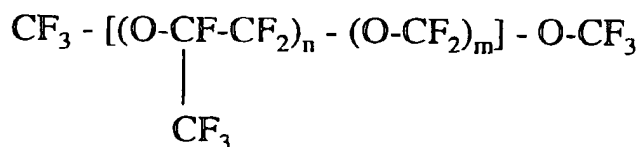
C.A.S. name: 1-Propene,1,1,2,3,3,3-hexafluoro-, oxidized and
polymerized C.A.S. number: 69991-67-9.

Appendix CPAGE 2 OF 3

RE: U.S. Patent Application No. 09/673,411
Applicant: Norberto FESTO
Title: Pharmaceutical Compositions Containing
Compounds...
Our Ref.: B-3992PCT 618156-1/JP/KST

Please replace the last paragraph on page 8 of the specification
(see page 8, lines 10-16) with the amended paragraph as set
forth below.

The invention is characterized by the claims at the end of this
description. According to the invention the pharmaceutical
compositions contain, apart from one or more active
ingredient(s), between 0.01 and 60% w/w of the compounds of
formula I



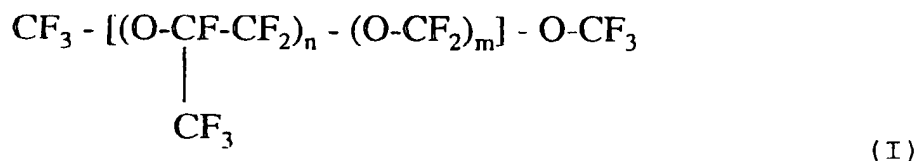
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Appendix CPAGE 3 OF 3

RE: U.S. Patent Application No. 09/673,411
Applicant: Norberto FESTO
Title: Pharmaceutical Compositions Containing
Compounds...
Our Ref.: B-3992PCT 618156-1/JP/KST

Please replace the last paragraph on page 9 of the specification
(see page 9, lines 12-23) with the amended paragraph as set
forth below.

The invention also includes the use of the compounds of formula
I



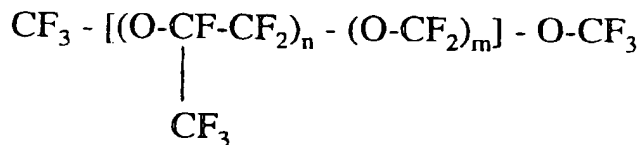
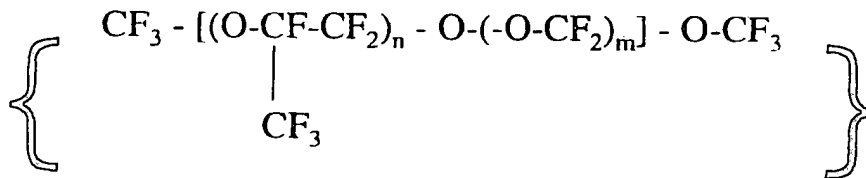
with n and m > 18 and < 46, preferably > 24 and < 36, and with
molecular weights between ~600 and ~8000, preferably between
1000 and 4000, in pharmaceutical compositions for topical
external or internal use for the enhancement of absorption of
active ingredients through the derma, cutis, mucosa, rectum,
vagina and urethra, with or without Phosphatidylcholine.
In particular, such use regards active ingredients that have
anabolic, analgesic, androgenic, anesthetic, anorectic,
anthelmintic, antiallergic, antiamebic, antiandrogenic,
antianginal, antiarrhythmic,

Appendix DPAGE 1 OF 4

RE: U.S. Patent Application No. 09/673,411
 Applicant: Norberto FESTO
 Title: Pharmaceutical Compositions Containing Compounds...
 Our Ref.: B-3992PCT 618156-1/JP/KST

Please amend the first paragraph on page 3 of the specification
 (see page 3, lines 1-8) as indicated below.

The term PFPE means molecules with a chemical structure



where $n/m = 20/40$

with molecular weights between 650 and 6250,

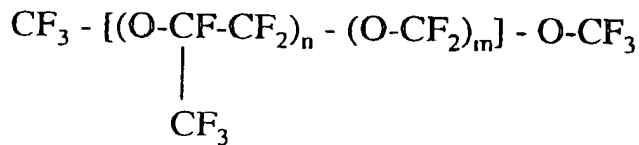
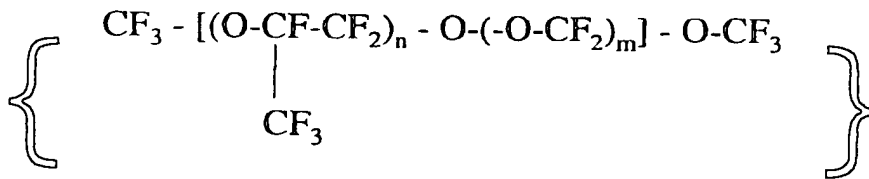
C.A.S. name: 1-Propene, 1,1,2,3,3,3-hexafluoro-, oxidized and
 polymerized C.A.S. number: 69991-67-9.

Appendix DPAGE 2 OF 4

RE: U.S. Patent Application No. 09/673,411
 Applicant: Norberto FESTO
 Title: Pharmaceutical Compositions Containing
 Compounds...
 Our Ref.: B-3992PCT 618156-1/JP/KST

Please amend the last paragraph on page 8 of the specification
 (see page 8, lines 10-16) as indicated below.

The invention is characterized by the claims at the end of this
 description. According to the invention the pharmaceutical
 compositions contain, apart from one or more active
 ingredient(s), between 0.01 and 60% w/w of the compounds of
 formula I



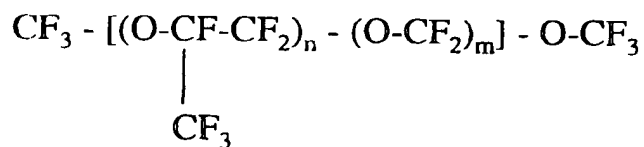
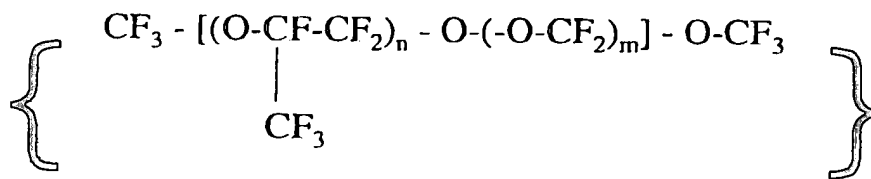
(I)

Appendix DPAGE 3 OF 4

RE: U.S. Patent Application No. 09/673,411
 Applicant: Norberto FESTO
 Title: Pharmaceutical Compositions Containing
 Compounds...
 Our Ref.: B-3992PCT 618156-1/JP/KST

Please amend the last paragraph on page 9 of the specification
 (see page 9, lines 12-23) as indicated below.

The invention also includes the use of the compounds of formula
 I



(I)

with n and m > 18 and < 46, preferably > 24 and < 36, and with
 molecular weights between ~600 and ~8000, preferably between
 1000 and 4000, in pharmaceutical compositions for topical
 external or internal use for the enhancement of absorption of
 active ingredients through the derma, cutis, mucosa, rectum,
 vagina and urethra, with or without Phosphatidylcholine.

APPENDIX DPAGE 4 OF 4

In particular, such use regards active ingredients that have
anabolic, analgesic, androgenic, anesthetic, anorectic,
anthelmintic, antiallergic, antiamebic, antiandrogenic,
antianginal, antiarrhythmic,

Appendix EPAGE 1 OF 1

RE: U.S. Patent Application No. 09/673,411

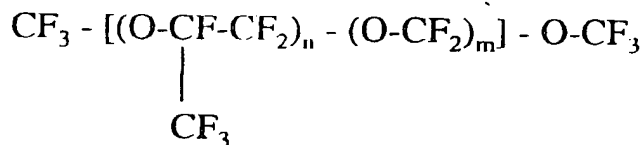
Applicant: Norberto FESTO

Title: Pharmaceutial Compositions Containing Compounds...

Our Ref.: B-3992PCT 618156-1/JP/KST

Please replace the abstract with the amended abstract as set forth below.

The new pharmaceutical compositions contain, apart from one or more active ingredient(s), between 0.01 and 60% w/w of the compounds of formula I



(I)

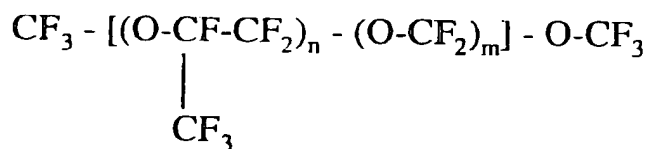
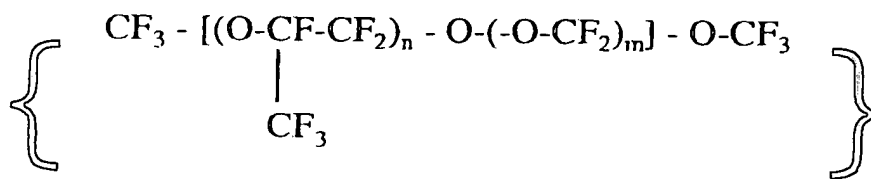
with n and m > 18 and < 46 and with molecular weights between ~600 and ~8000 for the enhancement of absorption of the active ingredient(s). Moreover, such compositions may contain also between 0.01 and 20% w/w of Phosphatidylcholine.

Appendix FPAGE 1 OF 1

RE: U.S. Patent Application No. 09/673,411
 Applicant: Norberto FESTO
 Title: Pharmaceutical Compositions Containing Compounds...
 Our Ref.: B-3992PCT 618156-1/JP/KST

Please amend the abstract as indicated below.

The new pharmaceutical compositions contain, apart from one or more active ingredient(s), between 0.01 and 60% w/w of the compounds of formula I



(I)

with n and m > 18 and < 46 and with molecular weights between ~600 and ~8000 for the enhancement of absorption of the active ingredient(s). Moreover, such compositions may contain also between 0.01 and 20% w/w of Phosphatidylcholine.

APPENDIX G

RE: U.S. Patent Application No. 09/673,411
Applicant: Norberto Festo
Title: "Pharmaceutical Compositions Containing . . ."
Our Ref.: 618156-1/JP/KST/B-3992PCT

✓
Please add new Claims 18-38, which are set forth below.

-
18. The composition according to Claim 1, wherein trans-absorption of the active ingredient is increased by up to more than five times its normal value.
19. The composition according to Claim 3, wherein trans-absorption of the active ingredient is increased by up to more than five times its normal value.
20. The method according to claim 13, wherein the active ingredient has an anabolic, an androgenic, an anesthetic, an anorectic, an anthelmintic, an antiallergic, an antiamebic, an antiandrogenic, an antianginal, an antiarrhythmic, an antiarteriosclerotic, an antiarthritic and an antirheumatic, an antibacterial, an anticholigenic, an anticonvulsant, an antidepressant, an antidiabetic, an antidiarrheal, an antidiuretic, an antiestrogenic, an antibiotic, an antiglaucoma, an antigonatropic, an antihistaminic, an antihyperlipoproteinemic, an antihyperthyroid, an antihypertensive, an antiinflammatory, an antimalarial, an antimigraine, an antinauseant, an antineoplastic, an antiparkinsonian, an

APPENDIX G

antiprotozoal, an antipruritic, an antopsoriatic, an antipsychotic, an antipyretic, an antiseptic, an antispasmodic, an antithrombotic, an antitussive, an antiulcer, an antiviral, an anxiolytic, a bronchodilator, a Ca-blocking or regulating, an cardiogenic, a stimulating, a decongestant, a diuretic, or an enzymatic effect.

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21. The method according to Claim 13, wherein the active ingredient has an anabolic, an analgesic, an androgenic, an anesthetic, an anorectic, an anthelmintic, an antiallergic, an antiamebic, an antiandrogenic, an antianginal, an antiarrhythmic, an antiarteriosclerotic, an antiarthritic and an antirheumatic, an antibacterial, an anticholinergic, an anticonvulsant, an antidepressant, an antidiabetic, an antidiarrheal, an antidiuretic, an antiestrogenic, an antibiotic, an antiglaucoma, an antigonatropic, an antihistaminic, an antihyperlipoproteinemic, an antihyperthyroid, an antihypertensive, or an anti-Pentifylline effect.

22. The method according to claim 13, wherein the active ingredient comprises an alpha-adrenergic agonist, a beta-adrenergic blocker, an alcohol deterrent, an aldose reductase inhibitor, an anabolic drug, a dental analgesic, a narcotic analgesic, a non-narcotic analgesic, an androgen, an intravenous anesthetic, an anorectic, an anthelmintic, an antiacne drug, an antiallergic drug, an antiamebic drug, an antiandrogen, an antianginal drug, an antiarrhythmic drug, an antiarteriosclerotic drug, an antiarthritic/antirheumatic drug, an antibacterial drug, a beta-lactam, a synthetic

APPENDIX G

antibacterial drug, an anticholinergic drug, an anticonvulsant drug, an antidepressant drug, an antidiabetic drug, an antidiarrheal drug, an antidiuretic drug, an antiestrogen drug, an antifungal drug, a synthetic antifungal drug, an antiglaucoma drug, an antigonadotropin, an antigout drug, an antihistamine, an antihyperlipoproteinemic drug, an antihypertensive drug, an antihyperthyroid drug, an antihypotensive drug, an antihypothyroid drug, a non-steroidal anti-inflammatory drug, an antimalarial drug, an antimigraine drug, an antinauseant drug, an antineoplastic drug, a hormonal antineoplastic drug, an antineoplastic adjunct drug including folic acid replenishers, an antiparkinsonian drug, an antipheochromocytoma drug, an antipneumocystis drug, an antiprostatic hypertrophy drug, an antiprotozoal drug, an antipuritic drug, and antipsoriatic drug, and antipsychotic drug, an antipyretic, an antirickettsial drug, an antiseborrheic drug, an antiseptic, an antispasmodic drug, an antithrombotic drug, an antitussive drug, and antiulcerative drug, an antiurolithic drug, an antivenin drug, an antiviral drug, an anxiolytic drug, a benzodiazepine antagonist, a bronchodilator, a calcium channel blocker, a calcium regulator, a cardiogenic, a chelating agent, a cholecystokinin antagonist, a cholelitholytic agent, a choleretic, a cholinergic agent, a cholinesterase inhibitor, a cholinesterase reactivator, a central nervous system stimulant, a central nervous system agent, a decongestant, a dental caries prophylaxis, a depigmentor, a diuretic, a dopamine receptor agonist, an ectoparasiticide, an enzyme, an hepatic enzyme inducer, an estrogen, a gastric secretion inhibitor, a glucocorticoid, a gonad stimulating principle, a gonadotropic hormone, a growth

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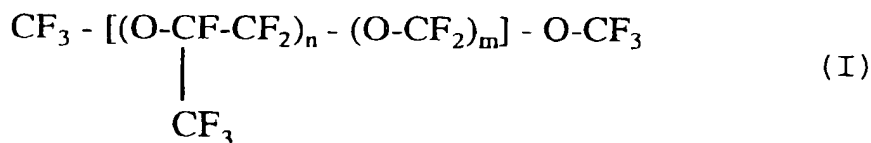
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hormone inhibitor, a growth hormone releasing factor, a growth stimulant, a hemolytic agent, a heparin antagonist, a hepatoprotectant, an immunomodulator, an immunosuppressant, an ion exchange resin, a lactation stimulating hormone, an LH-RH agonist, a lipotropic agent, a lupus erythematosus suppressant, a mineralcorticoid, a miotic drug, a monoamine oxidase inhibitor, a mucolytic agent, a skeletal muscle relaxant, a narcotic antagonist, a neuroprotective agent, a nootropic agent, an ophthalmic agent, an ovarian hormone, an oxytocic drug, a pepsin inhibitor, a peristaltic stimulant, a progestogen, a prolactin inhibitor, a prostaglandin and prostaglandin analog, a protease inhibitor, a respiratory stimulant, a sclerosing agent, a sedative and hypnotic drug, a thrombolytic agent, a thyrotropic hormone, a uricosuric drug, a cerebral vasodilator, a coronary vasodilator, a peripheral vasodilator, a vasoprotectant, a vitamin, a vitamin source, a vitamin extract, or a vulnerary agent.

23. (New) A method for enhancing absorption of an active ingredient, wherein the method comprises topically applying the pharmaceutical composition claimed in Claim 3 to a patient in need thereof, wherein the active ingredient is absorbed through derma, cutis, mucosa, rectum, vagina, or urethra.
24. A method as claimed in Claim 13, wherein the active ingredient comprises an anthelmintic that is effective against Cestodes, Nematodes, Onchocerca, Schistosoma, or Trematodes, or wherein the active ingredient comprises an antiprotozoal drug that is effective against Leshmania, Trichomonas, or Trypanosma.

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25. A pharmaceutical composition as claimed in Claim 1, wherein wherein trans-absorption of the active ingredient is increased by up to more than ten times its normal value.
26. A pharmaceutical composition as claimed in Claim 1, wherein wherein trans-absorption of the active ingredient is increased by up to more than 20 times its normal value.
27. A method as claimed in Claim 13, wherein trans-absorption of the active ingredient is increased by up to more than ten times its normal value.
28. A method as claimed in Claim 13, wherein trans-absorption of the active ingredient is increased by up to more than 20 times its normal value.
29. A pharmaceutical composition as claimed in Claim 1, wherein the active ingredient comprises troxerutine.
30. A method as claimed in Claim 13, wherein the active ingredient comprises troxerutine.
31. A pharmaceutical composition consisting essentially of:
- (1) one or more active ingredients;
 - (2) between about 0.01 per cent and about 60 per cent by weight of a compound of formula I



APPENDIX G

wherein n and m are each greater than 18 and are each less than 46 and wherein the compound of the formula I has a molecular weight between about 600 and about 8,000;

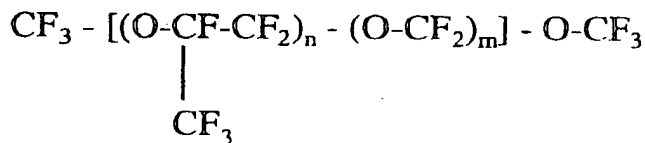
- (3) phosphatidylcholine;
- (4) optionally tocopherol acetate;
- (5) optionally polyacrylamide, C₁₃-C₁₄ isoparaffin, and

laureth-7;

- (6) optionally methyl-p-hydroxybenzoate;
- (7) optionally propyl-p-hydroxybenzoate;
- (8) optionally phenoxyethanol;
- (9) optionally nor-chenodeoxycolic acid;
- (10) optionally transcitol; and
- (11) optionally water.

32. A pharmaceutical composition consisting essentially of:

- (1) one or more active ingredients;
- (2) between about 0.01 per cent and about 60 per cent by weight of a compound of formula I



(I)

wherein n and m are each greater than 18 and are each less than 46 and wherein the compound of the formula I has a molecular weight

APPENDIX G

between about 600 and about 8,000;

- (3) phosphatidylcholine;
- (4) optionally tocopherol acetate;
- (5) optionally polyacrylamide, C₁₃-C₁₄ isoparaffin, and laureth-7;

- (6) optionally methyl-p-hydroxybenzoate;
- (7) optionally propyl-p-hydroxybenzoate;
- (8) optionally phenoxyethanol;
- (9) optionally nor-chenodeoxycolic acid;
- (10) optionally transcitol;
- (11) optionally lactic acid;
- (12) optionally ethyl alcohol; and
- (13) optionally water.

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33. A pharmaceutical composition as claimed in Claim 31, wherein the active ingredient comprises troxerutine.

34. A pharmaceutical composition according to claim 31, wherein the phosphatidylcholine constitutes 0.01 per cent to 10 per cent by weight of the pharmaceutical composition, and wherein the compound of the formula I has a molecular weight between 1,000 and about 4,000 with n and m each greater than 24 and each less than 36.

35. A pharmaceutical composition according to claim 33, wherein the phosphatidylcholine constitutes 0.01 per cent to 10 per cent by weight of the pharmaceutical composition, and wherein the compound of the formula I has a molecular weight between 1,000 and about 4,000 with n and m each greater than 24 and each less than

APPENDIX G

36.

36. A pharmaceutical composition as claimed in Claim 32, wherein the active ingredient comprises troxerutine.

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37. A pharmaceutical composition according to claim 32, wherein the phosphatidylcholine constitutes 0.01 per cent to 10 per cent by weight of the pharmaceutical composition, and wherein the compound of the formula I has a molecular weight between 1,000 and about 4,000 with n and m each greater than 24 and each less than 36.

38. A pharmaceutical composition according to claim 36, wherein the phosphatidylcholine constitutes 0.01 per cent to 10 per cent by weight of the pharmaceutical composition, and wherein the compound of the formula I has a molecular weight between 1,000 and about 4,000 with n and m each greater than 24 and each less than 36.

**GE Silicones**

SF1632

SF1632
Silicone Alkyl Copolymer

Product Description SF1632 is a linear polysiloxane functionalized with branched and linear alkyl groups. Specifically, SF1632 copolymer incorporates 32% branching. The result of this structure is a soft waxy material which is easy to formulate, provides excellent lubricity and spreadability and has good occlusive (TEWL) properties.

INCI NAME

Cetearyl Methicone

Key Performance Properties

- Excellent lubricity and spreadability
- Occlusive Properties
- Silicone Petrolatum - TEWL performance similar to petrolatum
- Moisturizing properties of petrolatum/aesthetics of silicone
- Good compatibility with organics

Applications SF1632 silicone alkyl copolymer can be used as a moisturizing emollient in the following types of products. Normal usage levels range from 2-10%.

- Protective Skin Products
- Sun Care Products
- Hand and/or Body Lotions
- Facial Products
- Barrier Creams

FORMULATIONS

Product formulations appearing in this product data sheet are included as illustrative examples only. GE Silicones makes no representation or warranty concerning the efficacy or safety of any product manufactured using such formulations. All statements concerning the possible use of

GE Silicone products are for research purposes only.
Responsibility for the performance or adequate testing of any product prior to sale or use of such product lies with the manufacturer thereof.

Typical Product Data

Property	Value
Free Olefin, %	20 max.
Melt Point, °C	25-35
Density lbs/gal	6.76
Color, (Gardner)	1
Flash Point, °C (°F)	> 100 (> 212)

Typical Product Data SOLUBILITY DATA

Key: I = Insoluble at < 1% by weight
PS = Partially Soluble at 1-10% by weight
S = Soluble at 10% or higher
SH = Soluble Hot at 10% or higher

SOLVENT TYPE	MATERIAL	SF1632
Highly Polar	Water	I
Hydrocarbon Solvents	Aliphatic Aromatic	S S
Hydrocarbon & Vegetable Oils	Mineral oil 65/75 SUS	S
	Mineral oil 200/210 SUS	S
	Petrolatum	SH
	Cottonseed (Gossypium) Oil	SH
	Castor (Ricinus Communis) Oil	I
	Sunflower (Helianthus Annuus) Seed Oil	PS
	Maleated Soybean Oil	PS
	Wheat (Triticum Vulgare) Germ Oil	PS
Alcohols & Glycols	Cetyl Alcohol	SH
	Ethanol 95%	I
	SD Alcohol 40	I
	Isopropyl Alcohol	S
	2-Ethyl-Hexanol	S
	Lauryl Alcohol	S
	Stearyl Alcohol	SH
	Ethylene Glycol	SH
	Propylene Glycol	I
	Glycerin	I
Esters	Isopropyl Palmitate	S
	Isopropyl Myristate	S
	Myristyl Propionate	S
	PPG-2 Myristyl Ether Propionate	S

Typical Product Data

Silicones	Dimethicone (SF 96-350)	I
	Cyclopentasiloxane (SF1202)	SH
	Diisostearoyl Trimethylolpropane Siloxy Silicate (SF1318)	S
	Phenyl Trimethicone (SF1550)	S
Waxes	Paraffin	SH
	Ozokerite	SH
	Candelilla (Euphorbia Cerifera) Wax	SH
	Beeswax	SH
	Carnauba(Copernicia Cerifera) Wax	SH
Sunscreens	Octyl Dimethyl PABA	I
	Benzophenone-3	I
	Octyl Methoxycinnamate	I
	Octyl Salicylate	S
Pigments	D& C Orange No. 5	I
	D& C Red No. 21	I
	Iron Oxides	I
Lanolin	Lanolin USP	SH
Other	Tocopheryl Acetate	PS

Typical Product Data TRANSEPIDERMAL WATER LOSS TESTING

Typical results describing the transepidermal water loss properties of SF1632 are summarized in the following table. The change in transepidermal water loss (Δ TEWL) was compared to that of petrolatum, since petrolatum is widely recognized as having excellent occlusive properties, and to a polydimethylsiloxane fluid, which was chosen for its high permeability to gases such as water vapor.

Transepidermal Water Loss study g/m²h measured at 21°C, 38% RH

	Δ TEWL (%)	
SAMPLE	2 hours	4 hours
Blank	-3.13%	-4.17%
Silicone fluid ^b	-5.53	-7.04
Alkyl silicone copolymer	-27.27	-25.36
Petrolatum ^a	-39.71	-27.27

^aVaseline™ Petroleum Jelly
^bSF 96-350 GE Silicones

Specifications Typical Product Data values should not be used as specifications. Assistance and recommendations are available by contacting GE Silicones at 800/255-8886.

SF1632 is a trademark of General Electric Company

REGULATORY STATUS

SF1632 silicone alkyl copolymer is not listed on the TSCA, 40CFR720. SF1632 is sold for FDA regulated applications only. It is contrary to U.S. Law to use this product for a TSCA regulated purpose.

Instructions for Use FORMULATING WITH SF1632 MOISTURIZING FACIAL LOTION

MATERIALS	PART WT (%)
PART A	
Deionized Water	76.58
Tetrasodium EDTA	0.02
Propylene Glycol	3.00
Panthenol	0.50
Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Propylparaben (and) Butylparaben ¹	0.80
PART B	
Cetearyl Methicone (SF1632) ²	5.00
Dicaprylyl Ether	4.00
Floraester-20	3.00
Maleated Soybean Oil	4.50
Cetyl Alcohol	1.00
PART C	
Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7 ³	1.40
Floral Fragrance	0.20

PROCEDURE

1. Heat water of Part A to 75°C with moderate propeller agitation. Add remaining ingredients in order listed with moderate stirring.
2. Combine Part B and heat to 75°C with slow agitation. Add Part B to Part A with moderate propeller agitation. Mix for 5 minutes then begin cooling batch to 60°C.
3. At 60°C add Part C (Sepigel then fragrance) to Part AB and mix with rapid propeller agitation until uniform and viscosity increases. As viscosity develops, increase mixing speed.
4. Cool to room temperature with adequate agitation.

SUPPLIERS

- 1 Phenonip®, Nipa Laboratories
2 GE Silicones
3 Sepigel ® 305, SEPPIC

Instructions for Use HAND AND BODY LOTION FOR DRY SKIN

MATERIALS	PART WT(%)
PART A	
Deionized Water	73.53
Disodium EDTA	0.02
Butylene Glycol	3.00
Panthenol	0.40
Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Propylparaben (and) Butylparaben ¹	0.80
PART B	
Cyclopentasiloxane (SF1202) ²	5.00
Cetearyl Methicone (SF1632) ²	10.00
Glyceryl Stearate (and) PEG-100 Stearate	1.00
Tocopherol (and) Cococaprylate/ Caprate	0.50
PART C	
Polyacrylamide (and) C13-14 Isoparaffin (and) Laureth-7 ³	1.40
PART D	
Fragrance ⁴	0.35
Aluminum Starch Octenylsuccinate	4.00

PROCEDURE

1. Heat water of PART A to 75°C with moderate propeller agitation. Add remaining ingredients in order listed with moderate stirring.
2. Combine PART B and heat to 75°C with slow agitation. Add PART B to PART A with moderate propeller agitation. Mix for 5 minutes then begin cooling batch.
3. At 50°C add PART C to PART AB and mix with rapid propeller agitation until uniform and viscosity increases. Mix 10 minutes with moderate homogenizer agitation. Cool to 45°C
4. Add PART D to batch in order listed and mix with moderate propeller agitation for 15 minutes. 5. Cool to room temperature with continued stirring.

SUPPLIERS

- 1 Phenonip®, Nipa Laboratories
2 GE Silicones
3 Sepigel 305 - Seppic
4 Fragrance HJ-416 - Shaw Mudge

Instructions for Use AFTER SHAVE LOTION

MATERIALS	PART/WT (%)

PART A	
Deionized Water	58.11
Disodium EDTA	0.02
SD Alcohol 40	15.00
Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Propylparaben (and) Butylparaben ¹	0.60
Sorbitol 70%	3.00
PART B	
Cyclopentasiloxane (SF1202) ²	5.00
Cetearyl Methicone (SF1632) ²	8.00
Bisabolol	0.20
Tocopheryl Acetate	0.20
Coco-Caprylate/Caprate	0.80
Aluminum Starch Octenylsuccinate	5.00
Polysorbate-85	1.50
PART C	
Fragrance ³	1.00
D& C Green No. 5 (0.1% solution)	0.07

PROCEDURE

1. Combine Part A at room temperature and mix for 15 minutes with moderate propeller agitation.
2. Combine Part B and mix with moderate propeller agitation for 20 minutes until uniform.
3. Add Part B to Part A SLOWLY with moderate stirring. Continue mixing for 15 minutes.
4. Add Part C to Part AB and mix with moderate propeller agitation for 20 minutes.

SUPPLIERS

¹ Phenonip®, Nipa Laboratories

² GE Silicones

³ Shaw-Mudge

Handling and Safety Material Safety Data Sheets are available upon request from GE Silicones. Similar information for solvents and other chemicals used with GE products should be obtained from your suppliers. When solvents are used, proper safety precautions must be observed.

Storage and Warranty Period The warranty period is 12 months from date of shipment from GE Silicones if stored in the original unopened container at 25°C (77°F).

Availability Products may be ordered from GE Silicones, Waterford, NY 12188, the GE Silicones sales office nearest you, or where appropriate, an authorized GE Silicones product distributor. They are available in the following container sizes and net weights:

Product	5 gal	55gal
SF1632	40lbs (18.1 kg)	370lbs (167.8 kg)

Government Requirement Prior to considering use of a GE Silicone product in fulfilling any government requirement, please contact the Government and Trade Compliance office at 413-448-4624.

CDS4788

LEGAL DISCLAIMER

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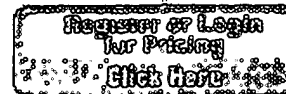
Each user bears the full responsibility for making its own determination as to the suitability of Supplier's materials, products, services, recommendations or advice for its own particular purpose. Each user must identify and perform tests and analyses sufficient to assure it that its finished parts will be safe and suitable for use under end-use conditions. Because actual use of products by the user is beyond the control of Supplier, such use is within the exclusive responsibility of the user, and Supplier cannot be held responsible for any loss incurred through incorrect or faulty use of the products. Further, no statement contained herein concerning a possible or suggested use of any material, product, service or design is intended or should be construed to grant any license under any patent or other intellectual property right of Supplier or any of its subsidiaries or affiliated companies, or as a recommendation for the use of such material, product, service or design in the infringement of any patent or other intellectual property right.

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Product Number: 374458

Product Name: Poly(perfluoropropylene xide-co-perfluorof rmaldehyde)

[Product Information](#)[Description](#)[Certificate of Analysis](#)[MSDS](#)[Structure Image](#)[References](#)[Print Preview](#)[Bulk Quote](#)[Ask A Scientist](#)[Product Suggestion Box](#)**Molecular Formula:** $[-CF(CF_3)CF_2O-]_x(-CF_2O-)_y$ **CAS:** 69991-67-9**MDL Number:** MFCD00134390**Density:** 1.865**Comments:** Refractive Index: <1.3000**Flash Point ("F):** >230**Product Comments:** Lubricant. Average M_n ca. 1,500. Ratio of x to y ca. 30:1

Polymer is made by an oxidative polymerization of hexafluoropropylene and tetrafluoroethylene. A representative structure is shown.

Applications: High performance lubricant for textile, bearing, and corrosive environment applications.**Miscellaneous:** *This chemical is in the EPA inventory under TSCA.*